

REMARKS

Claims 44-49 are active in this application. Claims 50-55 have been cancelled due to the Examiner's imposition of a restriction requirement.

The only issue remaining in this application is whether the present claims, i.e., Claims 44-49 are obvious in view of Brisson-Noel et al under the meaning of 35 U.S.C. § 103(a).

Applicants reiterate that Brisson-Noel et al do not, nor could, enable one to sequence the entire sequence of the plasmid to search for the coding regions because the plasmid and the bacteria from which the sequences were originally isolated were NOT in the public's possession. It was not until the filing and publication of the application to which the present application claims priority that the sequences themselves became available to the public. Notwithstanding Applicants prior analysis providing detailed reasons, supported by relevant case law and MPEP citations, that Brisson-Noel do not enable the claimed invention, the Examiner has found the analysis not persuasive (see page 5 of the Official Action). In support of the Examiner's position, four publications were provided: Roper et al (published in 2000), Tremlett et al (published in 1999), Kawalec et al (published in 2000), and Darini et al (published in 1999). However, as is readily apparent these documents were published at least 9 years after the filing of the application from which the present application claims priority. As a result, these documents are NOT evidence that the BM41147 or the plasmid pIP816 were available to the public prior to the filing of the application from which the present application claims priority. What these documents support is that some significant time after the patent application was filed that the plasmid and strain became available to the public.

Applicants point out that one of the necessary criteria for establishing a *prima facie* case of obviousness is a "reasonable expectation of success" which must be "found in the prior art, not in applicant's disclosure." (M.P.E.P. § 2143 and *In re Vaeck*, 947 F.2d 488, 20 USPQ2d

1438 (Fed. Cir. 1991). Here, the prior art cited cannot support any reasonable expectation of success because it is clear that the Brisson-Noel et al do not enable the bacteria or sequences from which one could sequence the entire plasmid insert, identify coding regions, and formulate a composition of coding regions to confer resistance to vancomycin as in the present claims.¹

Therefore, there is no evidence that prior to the present invention BM41147 or the plasmid pIP816 were available to the public prior to the filing of the application from which the present application claims priority and as a result Brisson-Noel does not support a *prima facie* case of obviousness.

Withdrawal of the rejection is requested.

¹ 37 C.F.R. § 1.801-1.809 and MPEP, Chapter 2400): "When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification." (*In re Lundak*, 227 USPQ 90, 93-94 (Fed. Cir. 1985)). See also MPEP § 2402 and *Ajinomoto Co. v Archer Daniels-Midland, Co.*, 56 USPQ2d 1332, 1337-1338: "The deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description or that constitute unique biological materials which can not be duplicated."

Applicants submit that the present application is now in a condition for allowance.

Early notification of such allowance is requested.

Respectfully submitted,

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A handwritten signature in black ink, appearing to be 'N. Oblon', written in a cursive style.

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